

Exhibit 2



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/237,605

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RICHARD J. LAZZARA

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EXAMINER

PREBLIC, PAUL B

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

10/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/237,605	LAZZARA ET AL.	
	Examiner	Art Unit	
	Paul B. Preblich	3774	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51 and 60-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51 and 60-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/7/2008</u> | 6) <input type="checkbox"/> Other, _____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 51 and 60-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki et al (the translation of Japanese patent JP3146679A2) or Wennerberg et al (Journal article entitled "Design and Surface Characteristics . . .") in view of Niznick (US 5,571,017).

Haruyuki discloses an acid etched titanium implant surface with recesses having average depths of 0.5 to 5 microns; see the English language abstract and the "Technical Field" paragraph on page 2. Haruyuki discloses making dental repair and biorepair members including bone fixation devices and artificial dental roots, but fails to disclose implants made with the macrofeatures of a head, a threaded portion and a lowermost end as claimed.

Likewise, Wennerberg discloses a wide variety of titanium implants with surface roughnesses known to the art including some with roughnesses under 10 micrometers; page 623, second column, fifth paragraph and page 624, Table 1, second column of numerical entries, "3I Miniplant, Ti" and "Nobelpharma" entries. Although Wennerberg discloses making screws and other implants, Wennerberg fails to disclose making the implant with macrofeatures of a head and a lowermost end as claimed.

However, Niznick teaches that it was known in the art to have different regions of roughness (where the roughened portion begins below surface (3) of Niznick), a tapered section (between (3) and (14) of Niznick or between sections (8) and (10) of Niznick), a smooth head portion (elements (2) and (3) of Niznick), a lowermost end (element (10) of Niznick) a roughened region that has a peak-to-valley roughness of less than 25 microns) and a self-tapping feature (element (8) of Niznick); see the abstract, Figure 1, column 2, lines 1-12, column 6, line 66 to column 7, line 24, column 4, lines 22-37, column 4, line 56 to column 5, line 6, and column 7, lines 9-24. Hence, it is the Examiner's position that it would have been obvious to have a smoother head portion, a threaded portion and a lowermost end in the Haruyuki invention for the same reasons that Niznick has the same.

With regard to the limitation pertaining to the minimum consumption of metal, the Examiner asserts that this process step would not affect the final surface property, and thus, the resultant product would be the same as one where there was a more than minimum consumption of metal; see MPEP 2113, which is incorporated herein by reference thereto.

With regard to claimed etching process steps that are considered to be product-by-process limitations, the Examiner posits that since a similar type of etching process is used to form irregularities on the surface of the same material as claimed that the surface irregularities of Haruyuki that Haruyuki's surfaces would inherently be substantially the same as those set forth in the claims; i.e. cone-shaped and/or spaced about the prescribed distance.

Regarding claim 63 and the cone-shaped irregularities claimed, upon review of Exhibit 1 and Exhibit B, Comparative Example 2 of the Dr. Gubbi declaration filed June 30, 2003, the Examiner concluded that the prior art treatments do result in cone-shaped elements; see the artifact folder color micrographs of Exhibit A (3D surface map of Appellants' Osseotite) thereof and compare to the color micrographs of Exhibit A of Examples 2 to 5 (3D surface maps of surfaces treated according to Haruyuki's treatment process). Thus, this evidence is used as evidence that cone-shaped elements are inherently present on the surface of Haruyuki.

Response to Arguments

In response to the argument filed July 10, 2008 that Haruyuki's surface is not inherently the same as the Applicant's surface, the Examiner asserts that Haruyuki's surface falls within the scope of the claims. After a review of the photographs filed with the response, the Examiner notes that the photographs are of poor quality such that little detail can be ascertained therefrom. Furthermore, the claimed invention is broader than any particular example, and the surface disclosed by Haruyuki falls within the claim scope.

In response to the arguments directed against the Haruyuki rejection that Haruyuki uses acid treatment to smoothen the surface not roughen it, the Examiner asserts that Haruyuki does not teach smoothening the surface. Rather, Haruyuki explains that there is an optimum surface characteristic to obtain for cell adhesion and ongrowth. Acid treatment with a too strong acid (over 6% HF) leads to too large of pores sizes while a too weak acid (under 1% HF) leads to too small of pores sizes; see

page 4, left column of the translation. "Smoothness" is not explicitly discussed. Rather, only rough edges and pores sizes are discussed. Furthermore, the fact that Haruyuki wants to optimize pores size and depth to promote cell attachment does not teach away from Niznick, but instead teaches a way of achieving what both references desire: cell attachment and ongrowth.

In response to the argument that Niznick teaches away from the combination with Haruyuki, the Examiner notes that analysis of the references does not match the actual language of the references; see page 8 of the response. In other words, the analysis has exaggerated the statements of the references. In particular, Haruyuki teaches that an average depth above 5 microns *"tends to result in the appearance of sharp edges at the ridge lines between the depressions, which can cause tissue irritation"* (emphasis added). Additionally, Niznick does not say that the roughness "must" be exceedingly rough as argued on page 8. The fact that Niznick teaches that certain areas of the implant are relatively rough does not constitute a teaching away.

Additionally, the Examiner asserts that since both references are concerned with rough surfaces for the purpose of ongrowth and ingrowth that the different dimensions alone do not make them incompatible. Disclosed embodiments or preferred embodiments do not constitute a teaching away; see MPEP 2123 (II) that is incorporated herein by reference.

The Applicant argues that Niznick teaches a different roughness than that claimed; see page 11 of the response. However, Niznick was not utilized to meet that limitation of the claim language. This argument is against the references individually.

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However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to Dr. Porter's Declaration, the claimed product-by-process steps are quite broad such that they are not commensurate in scope with the process steps used to make Applicant's samples; see the **First Test-Osseotite** on page 2 of the Dr. Gubbi's declaration filed June 30, 2003. From the description of the process, it is clear that very specific concentrations and treatment times were used that do not clearly exemplify a trend in the evidence; see MPEP 716.02(d) that is incorporated herein by reference. For these reasons, the Examiner asserts that evidence does clearly does not support a conclusion of unobviousness.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on March 7, 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilio whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilio/
Paul Prebilio
Primary Examiner
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